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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/542,520 | 04/03/2000 | W. James Jackson | 7969-076-999 | 4570 |

20583 7590 12/04/2001

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

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| EXAMINER |
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TURNER, SHARON L

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| ART UNIT | PAPER NUMBER |
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1647

DATE MAILED: 12/04/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/542,250

Applicant(s)
Jackson et al

Examiner
Sharon L. Turner, Ph.D.

Art Unit
1647



- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 9-21-01

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 21, 22, 32-37, and 42-47 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 21, 22, 32-37, and 42-47 are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

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DETAILED ACTION

1. Claims 21-22, 32-37 and 42-47 are pending.

Improper Markush

2. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the claims encompass multiple genus' molecules of high molecular weight proteins, analogues, fragments and recombinant proteins of variable structure as defined in the claims. These divergent structures fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 21-22, 32-37 and 42-47 to methods of administration to the extent of high molecular weight and recombinant protein of 105-115 kDa and analogues thereof, classified for example in class 530, subclasses 350.

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II. Claims 32-37 and 42-43 to methods of administration to the extent of fragments, classified for example in class 530, subclass 300.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions I and II are related as products. The products are distinct each from the other as the products are comprised of divergent structure, and exhibit different effects and function, for example differential immunogenic reactivity.

6. Furthermore, in addition to the election of one of the above II groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiment to which the claims will be restricted in accordance with the elected group:

A-R) A single designated amino acid composition of SEQ ID NO's:2, 3, 15, 16, 17, and 25-37, respectively as claimed.

7. The inventions are distinct, each from the other because of the following reasons:

8. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as A-R constitute patentably distinct inventions for the following reasons. Each of the polypeptides has unique structural features which require a unique search of the prior art. The inventions indicated as A-R differ in structure and function as they are composed of divergent amino acids and are differentially capable of stimulating immune responses. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search

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burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-II and a single molecular embodiment from designated groups A-R, even though the requirement is traversed. Applicant is advised that neither I-II nor A-R are species election requirements; rather each of I-II and A-R are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. It is noted that while one of A-R may not be applicable to one of I-II Applicant must elect one of

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each in order to be fully compliant. Applicant is further required to delineate the pending claims readable on the elected Groups I-II and A-R.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
December 2, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine Saoud